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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,622	03/18/2004	John McCafferty	05569.0004.DVUS11	6206

7590 04/10/2007

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EXAMINER	
STEELE, AMBER D	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,622	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 Decmeber 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 13, and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *March 18, 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-17 are currently pending.

Claims 1-8 and 10-12 are withdrawn from consideration.

Claims 9 and 13-17 are currently under consideration.

Election/Restrictions

2. This application contains claims (1-8) drawn to an invention nonelected without traverse in the response received on April 27, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of United Kingdom application 9015198.6 7/10/1990; United Kingdom application 9022845.3 10/19/1990; United Kingdom application 9024503.6 11/12/1990; United Kingdom application 9104744.9 3/6/1991; United Kingdom application 9110549.4 5/15/1991. The certified copies have been filed in parent Application No. 09/726,219, filed on November 28, 2000.

4. The priority for the present application is acknowledged as:

This application is a DIV of 09/726,219 11/28/2000 PAT 6,806,079 which is a CON of 08/484,893 06/07/1995 PAT 6,172,197 which is a CON of 07/971,857 01/08/1993 PAT

5,969,108 which is a National Stage application filed under 35 U.S.C. § 371 of PCT/GB91/01134 07/10/1991.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on December 22, 2006 is being considered by the examiner.

6. The information disclosure statement (IDS) submitted on October 18, 2004 was considered by the Examiner and mailed as an attachment to the Non-Final Office action on July 5, 2006. A typographical error in the Non-Final Office action occurred and therefore the Office action did not refer specifically to the October 18, 2004 IDS. However, the October 18, 2004 IDS was attached to the Office action mailed on July 5, 2006. In addition, applicants refer to an IDS filed on October 20, 2004, however, there is no record of an IDS filed on October 20, 2004.

7. The information disclosure statement (IDS) submitted on March 18, 2004 was considered **in part** and mailed as an attachment to the Non-Final Office action on July 5, 2006. The information expunged from the file of U.S. Application 09/726,219 (i.e. information related to U.S. District Court proceedings) was not considered. However, the U.S. Patent, foreign patent, and NPL references (i.e. publicly available information) was considered. Please refer to the attachment to the Non-Final Office action mailed on July 5, 2006.

Withdrawn Objections

8. The objection to the abstract is withdrawn in view of the amendment to the abstract received on December 22, 2006.

9. The objections to the specification are withdrawn in view of the amendments to the specification received on December 22, 2006.

10. The objection to the drawings/figures regarding the duplication of sequences in the drawings is withdrawn in view of applicants' arguments regarding alignments, ease of determining oligos in lengthy sequence listing, etc.

Withdrawn Rejections

11. The rejections of claims 9, 13, 14, 15, 16, and/or 17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent Nos. 5,969,108; 5,885,793; 6,521,404; 6,555,313; 6,582,915; 6,544,731; 6,593,081; and 6,916,605 and U.S. Patent Application No. 10/803,653 in view of the terminal disclaimers filed on December 22, 2006.

Maintained Rejections

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Please note that the rejections have been altered for clarification and to correct any typographical errors.

Claim Rejections - 35 USC § 102

13. Claims 9, 13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Dower et al. U.S. Patent 5,427,908 filed May 1, 1990.

For present claim 9, Dower et al. teach methods of producing filamentous bacteriophage surface expressing binding domains of antibody fragments including VH (e.g. dAb fragments)

that are encoded by nucleic acid sequences and screening the libraries of filamentous bacteriophage expressing the antibody fragments against various antigens, antigenetic determinants, or haptens in order to select a specific binding domain (please refer to abstract; columns 1-12; Example I).

For present claim 13, Dower et al. teach isolating the nucleic acid encoding the antibody fragments from spleen (i.e. peripheral lymphoid tissue, peripheral blood lymphocytes, B-lymphocytes; please refer to column 4 and Example 1).

For present claim 15, Dower et al. teach that the nonbound antibodies are washed away and the bound phage can be eluted from the antigen or hapten (please refer to column 10, lines 62-67; column 11, column 12, lines 1-23).

For present claim 16, Dower et al. teach that the previously antigen or hapten bound phage are recovered (please refer to column 11, lines 60-67; column 12, lines 1-31).

For present claim 17, Dower et al. teach recloning DNA from the eluted and recovered previously antigen or hapten bound phage particles via expression in a suitable eukaryotic or prokaryotic expression vector for production of large amounts of the binding domain protein (please refer to column 12, lines 32-41).

Therefore, the present invention is anticipated by the teachings of Dower et al.

Arguments and Response

14. Applicants' arguments directed to the rejection under 35 USC 102 (e) as being anticipated by Dower et al. for claims 9, 13, and 15-17 were considered but are not persuasive for the following reasons.

Applicants contend that Dower et al. does not teach dAb fragments or filamentous baceriophage.

Applicants' arguments are not convincing since the teachings of Dower et al. anticipate the method for producing a particular target epitope or antigen of the instant claims. Dower et al. specifically teach that the preferred phage are filamentous bacteriophage including M13, fd, and f1 (please refer to column 2, lines 14-61; column 7, lines 45-65; column 8, lines 31-57; column 9, lines 39-67; column 10, lines 1-46; Example 1). In addition, while Dower et al. does not specifically recite "dAb" or "dAb fragment", Dower et al. teaches producing libraries of VH and/**or** VL (e.g. library of VH expressing phage, library of VL expressing phage, library of VH and VL expressing phage). The present specification "defines" dAb as the VH (please refer to pages 3, 7, 30, and 48 of the present specification). Furthermore, Dower et al. teach producing libraries of Ab fragments or VH (please refer to column 3, lines 18-42; column 14, lines 40-67).

Claim Rejections - 35 USC § 103

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. WO 90/02809 published March 22, 1990 and Ladner et al. WO 88/06630 published September 7, 1988.

For present claim 9, Ladner et al. (WO 90/02809) teach methods of surface displaying binding domains on filamentous bacteriophage particles wherein the binding domains are encoded by nucleic acid sequences and then screened via binding to targets (please refer to abstract; pages 8-14; pages 17-18; pages 42-48).

However, while Ladner et al. (WO 90/02809) discuss the expression of scFv on the surface of filamentous phage, the expression of VH only is not taught.

For present claim 9, Ladner et al. (WO 88/06630) teach methods of surface displaying SCADs or antibody domain wherein "any protein or antibody domain for which a gene can be isolated or constructed may be displayed on the outer surface of an organism into which the gene has been inserted...by fusing the SCAD gene to the gene coding for a product which normally expresses on the surface of the organism" (e.g. VH) on the surface of Lamda phage and screening the SCADs against antigens (please refer to abstract; pages 2-6; Example 1; Figures 1-5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the methods of screening filamentous phage displaying proteins of Ladner et al. (WO 90/02809) with the SCADs or VH of Ladner et al. (WO 88/06630).

One having ordinary skill in the art would have been motivated to do this because Ladner et al. (WO 88/06630) teach that methods are needed to facilitate screening of antibody molecules to be more readily identified, recloned, and expressed (please refer to column 1, lines 25-48).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the methods of screening filamentous phage displaying proteins of Ladner et al. (WO 90/02809) with the SCADs or antibody fragments of Ladner et al. (WO 88/06630) because Ladner et al. (WO 90/02809) teach screening methods of phage-displayed proteins that are between 46 and 164 residues in length (e.g. VH approximately 100-120 residues in length; please refer to page 50, lines 29-35).

Therefore, the modification of the methods of screening filamentous phage displaying proteins of Ladner et al. (WO 90/02809) with the SCADs or antibody fragments (e.g. VH) of Ladner et al. (WO 88/06630) render the instant claim *prima facie* obvious.

Arguments and Response

16. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Ladner et al. et al. (WO 90/02809) and Ladner et al. (WO 88/06630) for claim 9 were considered but are not persuasive for the following reasons.

Applicants contend that the Ladner et al. references teach scFv/SCADs only (i.e. not dAbs). In addition, it is noted that applicants state that "[i]n dAbs, only a VH domain or a VL domain is present to form the binding domain". However, The present specification "defines" dAb as the VH (please refer to pages 3, 7, 30, and 48 of the present specification). Applicants also reference several U.S. Patents and U.S. Patent applications of Ladner that teach scFv (e.g. both a VH and VL domain). However, these references are not the art of record utilized for the rejection of claim 9.

Applicants' arguments are not convincing since the teachings of Ladner et al. (WO 90/02809) and Ladner et al. (WO 88/06630) render the method for producing a particular target epitope or antigen of the instant claims *prima facie* obvious. Ladner et al. (WO 88/06630) teach methods of surface displaying SCADs (i.e. single-chain antibody domain) or antibody domain wherein any protein or antibody domain (e.g. VH) for which a gene can be isolated or constructed may be displayed on the outer surface of an organism into which the gene has been inserted on the surface of Lamda phage and screening against antigens (please refer to abstract; pages 2-6; Example 1; Figures 1-5). In addition, Ladner et al. (WO 90/02809) teach screening methods of phage-displayed proteins that are between 46 and 164 residues in length (e.g. VH approximately 100-120 residues in length; please refer to page 50, lines 29-35).

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
March 27, 2007

MARK L. SHIBUYA
PRIMARY EXAMINER